

## Environmental Protection Agency

## §711.3

equipment in which they were manufactured.

NOTE: See note to definition of “intermediate” at §710.3(d) for explanation of “equipment in which it was manufactured.”

[42 FR 64572, Dec. 23, 1977, as amended at 68 FR 889, Jan. 7, 2003]

### PART 711—TSCA CHEMICAL DATA REPORTING REQUIREMENTS

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AUTHORITY: 15 U.S.C. 2607(a).

SOURCE: 76 FR 54933, Sept. 6, 2011, unless otherwise noted.

EDITORIAL NOTE: At 76 FR 50859, Aug. 16, 2011, part 711 was added; however, the amendment could not be incorporated because part 711 already existed.

#### §711.1 Scope and compliance.

(a) This part specifies reporting and recordkeeping procedures under section 8(a) of the Toxic Substances Control Act (TSCA) (15 U.S.C. 2607(a)) for certain manufacturers (including importers) of chemical substances. Section 8(a) of TSCA authorizes the EPA Administrator to require reporting of information necessary for administration of TSCA, including issuing regulations for the purpose of compiling and keeping current the TSCA Chemical Substance Inventory (TSCA Inventory) as required by TSCA section 8(b). In accordance with TSCA section 8(b), EPA amends the TSCA Inventory to include new chemical substances manufactured (including imported) in the United States and reported under TSCA section 5(a)(1). EPA also revises the categories of chemical substances and makes other amendments as appropriate.

(b) This part applies to the activities associated with the periodic update of information on a subset of the chemical substances included on the TSCA Inventory.

(c) Section 15(3) of TSCA makes it unlawful for any person to fail or refuse to submit information required under this part. In addition, TSCA section 15(3) makes it unlawful for any person to fail to keep, and permit access to, records required by this part. Section 16 of TSCA provides that any person who violates a provision of TSCA section 15 is liable to the United States for a civil penalty and may be criminally prosecuted. Pursuant to TSCA section 17, the Federal Government may seek judicial relief to compel submission of TSCA section 8(a) information and to otherwise restrain any violation of TSCA section 15. (EPA does not intend to concentrate its enforcement efforts on insignificant clerical errors in reporting.)

(d) Each person who reports under this part must maintain records that document information reported under this part and, in accordance with TSCA, permit access to, and the copying of, such records by EPA officials.

#### §711.3 Definitions.

The definitions in this section and the definitions in TSCA section 3 apply to this part. In addition, the definitions in 40 CFR 704.3 also apply to this part, except the definitions *manufacture* and *manufacturer* in 40 CFR 704.3.

*CDX* or *Central Data Exchange* means EPA's centralized electronic document receiving system, or its successors.

*Commercial use* means the use of a chemical substance or a mixture containing a chemical substance (including as part of an article) in a commercial enterprise providing saleable goods or services.

*Consumer use* means the use of a chemical substance or a mixture containing a chemical substance (including as part of an article) when sold to or made available to consumers for their use.

*e-CDRweb* means the electronic, web-based tool provided by EPA for the completion and submission of the CDR data.

*Industrial function* means the intended physical or chemical characteristic for which a chemical substance or mixture is consumed as a reactant; incorporated into a formulation, mixture, reaction product, or article; repackaged; or used.

*Industrial use* means use at a site at which one or more chemical substances or mixtures are manufactured (including imported) or processed.

*Intended for use by children* means the chemical substance or mixture is used in or on a product that is specifically intended for use by children age 14 or younger. A chemical substance or mixture is intended for use by children when the submitter answers “yes” to at least one of the following questions for the product into which the submitter’s chemical substance or mixture is incorporated:

(1) Is the product commonly recognized (i.e., by a reasonable person) as being intended for children age 14 or younger?

(2) Does the manufacturer of the product state through product labeling or other written materials that the product is intended for or will be used by children age 14 or younger?

(3) Is the advertising, promotion, or marketing of the product aimed at children age 14 or younger?

*Manufacture* means to manufacture, produce, or import, for commercial purposes. Manufacture includes the extraction, for commercial purposes, of a component chemical substance from a previously existing chemical substance or complex combination of chemical substances. When a chemical substance, manufactured other than by import, is:

(1) Produced exclusively for another person who contracts for such production, and

(2) That other person specifies the identity of the chemical substance and controls the total amount produced and the basic technology for the plant process, then that chemical substance is co-manufactured by the producing manufacturer and the person contracting for such production.

*Manufacturer* means a person who manufactures a chemical substance.

*Master Inventory File* means EPA’s comprehensive list of chemical sub-

stances which constitutes the TSCA Inventory compiled under TSCA section 8(b). It includes chemical substances reported under 40 CFR part 710 and substances reported under 40 CFR part 720 for which a Notice of Commencement of Manufacture or Import has been received under 40 CFR 720.120.

*Principal reporting year* means the latest complete calendar year preceding the submission period.

*Reasonably likely to be exposed* means an exposure to a chemical substance which, under foreseeable conditions of manufacture (including import), processing, distribution in commerce, or use of the chemical substance, is more likely to occur than not to occur. Such exposures would normally include, but would not be limited to, activities such as charging reactor vessels, drumming, bulk loading, cleaning equipment, maintenance operations, materials handling and transfers, and analytical operations. Covered exposures include exposures through any route of entry (inhalation, ingestion, skin contact, absorption, etc.), but excludes accidental or theoretical exposures.

*Repackaging* means the physical transfer of a chemical substance or mixture, as is, from one container to another container or containers in preparation for distribution of the chemical substance or mixture in commerce.

*Reportable chemical substance* means a chemical substance described in §711.5.

*Site* means a contiguous property unit. Property divided only by a public right-of-way shall be considered one site. More than one manufacturing plant may be located on a single site.

(1) For chemical substances manufactured under contract, i.e., by a toll manufacturer, the site is the location where the chemical substance is physically manufactured.

(2) The site for an importer who imports a chemical substance described in §711.5 is the U.S. site of the operating unit within the person’s organization that is directly responsible for importing the chemical substance. The import site, in some cases, may be the organization’s headquarters in the United States. If there is no such operating unit or headquarters in the United

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States, the site address for the importer is the U.S. address of an agent acting on behalf of the importer who is authorized to accept service of process for the importer.

(3) For portable manufacturing units sent to different locations from a single distribution center, the distribution center shall be considered the site.

*Site-limited* means a chemical substance is manufactured and processed only within a site and is not distributed for commercial purposes as a chemical substance or as part of a mixture or article outside the site. Imported chemical substances are never site-limited. Although a site-limited chemical substance is not distributed for commercial purposes outside the site at which it is manufactured and processed, the chemical substance is considered to have been manufactured and processed for commercial purposes.

*Submission period* means the period in which the manufacturing, processing, and use data are submitted to EPA.

*U.S. parent company* means the highest level company, located in the United States, that directly owns at least 50% of the voting stock of the manufacturer.

*Use* means any utilization of a chemical substance or mixture that is not otherwise covered by the terms manufacture or process. Relabeling or redistributing a container holding a chemical substance or mixture where no repackaging of the chemical substance or mixture occurs does not constitute use or processing of the chemical substance or mixture.

### §711.5 Chemical substances for which information must be reported.

Any chemical substance that is in the Master Inventory File at the beginning of a submission period described in §711.20, unless the chemical substance is specifically excluded by §711.6.

### §711.6 Chemical substances for which information is not required.

The following groups or categories of chemical substances are exempted from some or all of the reporting requirements of this part, with the following exception: A chemical substance described in paragraph (a)(1),

(a)(2), or (a)(4), or (b) of this section is not exempted from any of the reporting requirements of this part if that chemical substance is the subject of a rule proposed or promulgated under TSCA section 4, 5(a)(2), 5(b)(4), or 6, or is the subject of an enforceable consent agreement (ECA) developed under the procedures of 40 CFR part 790, or is the subject of an order issued under TSCA section 5(e) or 5(f), or is the subject of relief that has been granted under a civil action under TSCA section 5 or 7.

(a) *Full exemptions.* The following categories of chemical substances are exempted from the reporting requirements of this part.

(1) *Polymers*—(i) Any chemical substance described with the word fragments “\*polym,” “\*alkyd,” or “\*oxylated” in the Chemical Abstracts (CA) Index Name in the Master Inventory File, where the asterisk (\*) in the listed word fragments indicates that any sets of characters may precede, or follow, the character string defined.

(ii) Any chemical substance that is identified in the Master Inventory File as an enzyme, lignin, a polysaccharide (cellulose, gum, starch), a protein (albumin, casein, gelatin, gluten, hemoglobin), rubber, siloxane and silicone, or silsesquioxane.

(iii) This exclusion does not apply to a polymeric substance that has been depolymerized, hydrolyzed, or otherwise chemically modified, except in cases where the intended product of this reaction is totally polymeric in structure.

(2) *Microorganisms.* Any combination of chemical substances that is a living organism, and that meets the definition of *microorganism* at 40 CFR 725.3. Any chemical substance produced from a living microorganism is reportable under this part unless otherwise excluded.

(3) *Naturally occurring chemical substances.* Any naturally occurring chemical substance, as described in 40 CFR 710.4(b). The applicability of this exclusion is determined in each case by the specific activities of the person who manufactures the chemical substance in question. Some chemical substances can be manufactured both as described in 40 CFR 710.4(b) and by means other than those described in 40 CFR 710.4(b).